UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,137	03/23/2005	Michael Ziegler	82291	1505

23685 7590 03/20/2008

KRIEGSMAN & KRIEGSMAN
30 TURNPIKE ROAD, SUITE 9
SOUTHBOROUGH, MA 01772

EXAMINER	
FUJITA, KATRINA R	
ART UNIT	PAPER NUMBER
2624	
MAIL DATE	DELIVERY MODE
03/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,137	ZIEGLER, MICHAEL	
	Examiner	Art Unit	
	KATRINA FUJITA	2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27 and 29-40* is/are rejected.

7)☒ Claim(s) *28* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 July 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/23/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. This Office Action is responsive to Applicant's remarks received on July 19, 2004. Claims 1-40 remain pending.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 27.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate

prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The abstract of the disclosure is objected to because it contains reference numerals from the drawings. Correction is required. See MPEP § 608.01(b).

5. The disclosure is objected to because of the following informalities:

The first line of the specification does not include a sentence acknowledging applicant's claim for foreign priority. The examiner suggests amending the specification to include that information.

Appropriate correction is required.

Claim Objections

6. The following is a quotation of 37 CFR 1.75(a):

> The specification must conclude with a claim particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention or discovery.

7. Claims 1, 4, 7, 8, 14, 18, 20, 25, 26/24/20, 28 and 35 are objected to under 37 CFR 1.75(a), as failing to particularly point out and distinctly claim the subject matter which application regards as his invention or discovery.

Claim 1 lacks antecedent basis for "the body fluid" in line 2. The following will be assumed for examination purposes: -- ~~the~~ a body fluid --.

Claim 4 lacks antecedent basis for "the caps" in line 2. The following will be assumed for examination purposes: -- ~~the~~ caps --.

Claim 7 lacks antecedent basis for "the bar code" in line 4. The following will be assumed for examination purposes: -- ~~the~~ a bar code --.

Claim 8 lacks antecedent basis for "the optical blanking" in line 2. The following will be assumed for examination purposes: -- ~~the~~ an optical blanking --.

Claim 14 lacks antecedent basis for "the handling apparatus" in line 1. The following will be assumed for examination purposes: -- ~~the~~ a handling apparatus --. The same applies to claim 28, line 2.

Claim 18 lacks antecedent basis for "the separating means" in line 2. The following will be assumed for examination purposes: -- ~~the~~ separating means --.

Claim 18 lacks antecedent basis for "the blood clot" in line 3. The following will be assumed for examination purposes: -- ~~the~~ a blood clot --.

Claim 18 recites "a separating means" in line 6. It is unclear whether this is intended to be the same as or different from the "separating means" in line 2. The following will be assumed for examination purposes: -- ~~a~~ the separating means --.

Claim 20 lacks antecedent basis for "the region-grow method" in line 3. The following will be assumed for examination purposes: -- ~~the~~ a region-grow method --.

Claim 25 lacks antecedent basis for "the color value" in line 2. The following will be assumed for examination purposes: -- ~~the~~ a color value --.

Claim 25 lacks antecedent basis for "the serum" in line 3. The following will be assumed for examination purposes: -- ~~the~~ a serum --.

Claim 26/24/20 lacks antecedent basis for "the comparison" in line 1. The following will be assumed for examination purposes: -- ~~the~~ a comparison --.

Claim 35 lacks antecedent basis for "The storage medium as claimed in claim 33" in line 1. However, it appears that this is intended to depend from claim 34. Therefore, the following will be assumed for examination purposes: -- The storage medium as claimed in claim ~~33~~ 34 --.

8. The following is a quotation of 37 CFR 1.75(d)(1):

> The claim or claims must conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.

9. Claim 40 is objected to under 37 CFR 1.75(d)(1), as failing to conform to the invention as set forth in the remainder of the specification.

Claim 40 requires "data carrier, in particular a hard disk, a floppy disk, a CD ROM or a storage tape" at lines 2-3. The specification, while describing software, does not necessarily describe any of the particular data carriers as claimed. Thus the

specification does not provide "clear support or antecedent basis in the description" for the data carriers. Correction or clarification is required.

10. Claim 28 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claim 5 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation "the latter" in line 3. It is unclear what this is referring to. Looking back to claim 1, "the latter" could be referring to the "body fluid" in line 3 or the "container" in line 3. Further clarification is required. For the purposes of examination, the following will be assumed: -- the ~~latter~~ container --.

Regarding claim 22, the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the

claimed invention. See MPEP § 2173.05(d). Therefore, the limitation "for example 'red clots' and 'white clots'" will be given no weight for the purpose of examination.

Claim Rejections - 35 USC § 101

13. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The USPTO "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (Official Gazette notice of 22 November 2005), Annex IV, reads as follows:

> Descriptive material can be characterized as either "functional descriptive material" or "nonfunctional descriptive material." In this context, "functional descriptive material" consists of data structures and computer programs which impart functionality when employed as a computer component. (The definition of "data structure" is "a physical or logical relationship among data elements, designed to support specific data manipulation functions." The New IEEE Standard Dictionary of Electrical and Electronics Terms 308 (5th ed. 1993).) "Nonfunctional descriptive material" includes but is not limited to music, literary works and a compilation or mere arrangement of data.
>
> When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized. Compare In re Lowry, 32 F.3d 1579, 1583-84, 32 USPQ2d 1031, 1035 (Fed. Cir. 1994) (claim to data structure stored on a computer readable medium that increases computer efficiency held statutory) and Warmerdam, 33 F.3d at 1360-61, 31 USPQ2d at 1759 (claim to computer having a specific data structure stored in memory held statutory product-by-process claim) with Warmerdam, 33 F.3d at 1361, 31 USPQ2d at 1760 (claim to a data structure per se held nonstatutory).
>
> In contrast, a claimed computer-readable medium encoded with a computer program is a computer element which defines structural and functional interrelationships between the computer program and the rest of the computer which permit the computer program's functionality to be realized, and is thus statutory. See Lowry, 32 F.3d at 1583-84, 32 USPQ2d at 1035.

14. Claims 37-40 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter as follows. Claims 37-40 define a computer program product embodying functional descriptive material. However, the claims do not define a computer-readable medium or computer-readable memory and is thus non-statutory for that reason (i.e., "When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized" – Guidelines Annex IV). The scope of the presently claimed invention encompasses products that are not necessarily computer readable, and thus NOT able to impart any functionality of the recited program. The examiner suggests amending the claims to embody the program on "computer-readable medium" or equivalent; assuming the specification does NOT define the computer readable medium as a "signal", "carrier wave", or "transmission medium" which are deemed non-statutory (refer to "note" below). Any amendment to the claim should be commensurate with its corresponding disclosure.

Note:

A "signal" (or equivalent) embodying functional descriptive material is neither a process nor a product (i.e., a tangible "thing") and therefore does not fall within one of the four statutory classes of § 101. Rather, "signal" is a form of energy, in the absence of any physical structure or tangible material.

Should the full scope of the claim as properly read in light of the disclosure encompass non-statutory subject matter such as a "signal", the claim as a whole would be non-statutory. In the case where the specification defines the computer readable medium or memory as statutory tangible products such as a hard drive, ROM, RAM, etc, as well as a non-statutory entity such as a "signal", "carrier wave", or "transmission medium", the examiner suggests amending the claim to ***include*** the disclosed tangible computer readable media, while at the same time ***excluding*** the intangible media such as signals, carrier waves, etc.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 1-6, 11, 31-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Watson et al. (WO 99/28724).

Regarding **claim 1**, Watson et al. discloses a method for analyzing body fluids ("analyzer is arranged to detect the level of the sample" at page 6, line 23), characterized in that an image recording device (figure 8B, numeral 22) is used to produce at least one image of a body fluid located in a container ("image captured

through the window is conveniently employed for determining the level and/or volume of the sample available for analysis" at page 6, line 31) that is analyzed by means of image processing software ("Along with information in the windows for capturing characteristics of each type of tubes 14, in the memory are also stored information relating to corresponding brand, type, volume, gel content, etc. Therefore when a match or close match is determined, the computer can identify the type of tube" at page 23, line 21).

Regarding **claim 31**, Watson et al. discloses an apparatus for analyzing body fluids ("analyzer is arranged to detect the level of the sample" at page 6, line 23), characterized in that an image recording device (figure 8B, numeral 22) is provided and is connected to an electronic image evaluation apparatus ("computer of the controller" at page 21, line 6).

Regarding **claim 2**, Watson et al. discloses a method characterized in that firstly the type and size of the container are determined automatically ("captures the shape and colour of the cap" at page 20, line 13; "This allows the system to positively identify tubes 14 which have two colours on the top of the cap" at page 20, line 15).

Regarding **claim 3**, Watson et al. discloses a method characterized in that an image of the container is produced with the aid of the image recording device ("digital camera 22 also captures the dimensions of the tube" at page 20, line 17) and is compared with the aid of evaluation software with stored image files and/or dimensions of known containers ("Along with information in the windows for capturing characteristics of each type of tubes 14, in the memory are also stored information

relating to corresponding brand, type, volume, gel content, etc. Therefore when a match or close match is determined, the computer can identify the type of tube" at page 23, line 21).

Regarding **claim 4**, Watson et al. discloses a method characterized in that caps of the tubes holding the body fluid are compared ("captures the shape and colour of the cap" at page 20, line 13; "This allows the system to positively identify tubes 14 which have two colours on the top of the cap" at page 20, line 15), and the type of tube and height of tube are determined thereby ("digital camera 22 also captures the dimensions of the tube" at page 20, line 17).

Regarding **claim 5**, Watson et al. discloses a method characterized in that after determination of the type and size of the container, the container is moved automatically in such a way that as complete an image as possible of the body fluid can be produced by means of the image recording device ("In order that the specimen is correctly captured by the digital camera 22, a controller (not shown), upon receiving a signal from the reader 20, rotates a pair of gripper 146 holding the tube 14 by a predetermined angle so that the camera 22 can capture images of the sample through a portion or window of the tube 14 not obscured by the label 88 and the tube manufacture's label" at page 20, line 19).

Regarding **claim 6**, Watson et al. discloses a method characterized in that the container is moved automatically such that as complete an image as possible of the body fluid can be produced ("In order that the specimen is correctly captured by the digital camera 22, a controller (not shown), upon receiving a signal from the reader 20,

rotates a pair of gripper 146 holding the tube 14 by a predetermined angle so that the camera 22 can capture images of the sample through a portion or window of the tube 14 not obscured by the label 88 and the tube manufacture's label" at page 20, line 19).

Regarding **claim 11**, Watson et al. discloses a method characterized in that a color image of a body fluid and of the container is produced ("Take picture of full field view with 24 bit RGB colour depth" at page 22, line 7; "Create sub-images of areas used for tube identification" at page 22, line 8).

Regarding **claim 32**, Watson et al. discloses a computer programmed for carrying out the method ("controller is programmed to image predefined windows" at page 21, line 10).

Regarding **claim 33**, Watson et al. discloses an apparatus for analyzing body fluids ("analyzer is arranged to detect the level of the sample" at page 6, line 23), characterized in that an image recording device is provided (figure 8B, numeral 22) and is connected to an electronic image evaluation apparatus, said apparatus including at least one computer ("computer of the controller" at page 21, line 6).

Regarding **claim 34**, Watson et al. discloses a digital storage medium ("storage media" at page 22, line 1) having electronically readable control signals that can cooperate with a programmed computer system such that the method is executed ("controller is programmed to image predefined windows" at page 21, line 10).

Regarding **claim 35**, Watson et al. discloses a digital storage medium ("storage media" at page 22, line 1) that has control software for controlling ("controller is programmed to image predefined windows" at page 21, line 10) an apparatus for

analyzing body fluids ("analyzer is arranged to detect the level of the sample" at page 6, line 23), characterized in that an image recording device (figure 8B, numeral 22) is provided and is connected to an electronic image evaluation apparatus ("computer of the controller" at page 21, line 6).

Regarding **claim 36**, Watson et al. discloses a digital storage medium ("storage media" at page 22, line 1) that has image processing software for analyzing images ("Along with information in the windows for capturing characteristics of each type of tubes 14, in the memory are also stored information relating to corresponding brand, type, volume, gel content, etc. Therefore when a match or close match is determined, the computer can identify the type of tube" at page 23, line 21).

Regarding **claim 37**, Watson et al. discloses a computer program product for carrying out the method ("controller is programmed to image predefined windows" at page 21, line 10).

Regarding **claim 38**, Watson et al. discloses a computer program product, specifically control software for controlling ("controller is programmed to image predefined windows" at page 21, line 10) an apparatus for analyzing body fluids ("analyzer is arranged to detect the level of the sample" at page 6, line 23), characterized in that an image recording device (figure 8B, numeral 22) is provided and is connected to an electronic image evaluation apparatus ("computer of the controller" at page 21, line 6).

Regarding **claim 39**, Watson et al. discloses a computer program product, specifically image processing software for analyzing images ("Along with information in

the windows for capturing characteristics of each type of tubes 14, in the memory are also stored information relating to corresponding brand, type, volume, gel content, etc. Therefore when a match or close match is determined, the computer can identify the type of tube" at page 23, line 21).

17. Claims 1, 11 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Itsuzaki et al. (US 5,763,265).

Regarding **claim 1**, Itsuzaki et al. discloses a method for analyzing body fluids ("specimen testing method" at col. 1, line 5), characterized in that an image recording device (figure 7, numeral 22) is used to produce at least one image of the body fluid ("image of separated blood" at col. 4, line 35) located in a container (figure 7, numeral 1) that is analyzed by means of image processing software (figure 7, numeral 10-13 imply software).

Regarding **claim 11**, Itsuzaki et al. discloses a method characterized in that a color image of the body fluid and of the container is produced ("outputting the image as color digital image data" at col. 4, line 35).

Regarding **claim 16**, Itsuzaki et al. discloses a method characterized in that for the purpose of evaluating the image of a body fluid, a number of perpendicular and/or horizontal lines are laid in the image of the body fluid ("projection data row obtained by adding image data in every one of all horizontal lines in the boundary detection region" at col. 3, line 49), the color values and/or brightness values of the pixels lying on these lines are detected ("positions of peak differential values may be obtained" at col. 3, line

52, which correspond to image data values with particular intensities), changes in color value and/or brightness value are determined (the peak values indicate transition points), and a background region and/or upper edge of the body fluid are determined ("upper boundary 5" at col. 3, line 48).

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Watson et al. and Michelotti et al. (US 5,755,335).

Regarding **claim 7**, Watson et al. discloses a method characterized in that a scanner and/or image evaluation software are provided for detecting an inscription placed on the container ("controller is programmed to image predefined windows" at page 21, line 10), a label and/or a cover ("label 88 and the tube manufacture's label" at page 20, line 23), and in that the scanner detects a bar code (figure 8A, numeral 20) and the container is moved automatically such that the cover is situated on the side of the container averted from the image recording device ("In order that the specimen is correctly captured by the digital camera 22, a controller (not shown), upon receiving a

signal from the reader 20, rotates a pair of gripper 146 holding the tube 14 by a predetermined angle so that the camera 22 can capture images of the sample through a portion or window of the tube 14 not obscured by the label 88 and the tube manufacture's label" at page 20, line 19).

Watson et al. does not disclose detecting the edges of the cover.

Michelotti et al. teaches a method in the same field of endeavor of label inspection ("inspection of labels thereon" at col. 1, line 11) that detects the edges of the cover ("label edge detection system and rotationally orienting the container 12 based upon the detected label edge" at col. 8, line 50).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize the edge detection of Michelotti et al. to orient the containers of Watson et al. to ensure that the container may be consistently imaged by the camera.

Regarding **claim 8**, the Watson et al. and Michelotti et al. combination discloses the elements of claim 7 as described above.

The Watson et al. and Michelotti et al. combination does not disclose following an optical blanking out of a cover the container is covered on the side averted from the image recording device.

However, Watson et al. does disclose optical blanking out image data ("Blank out unused areas (cap area, bottom radius) using the physical properties of the tube" at page 23, line 1).

Therefore, it would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize the image blanking of Watson et al. on the label of the

Watson et al. and Michelotti et al. combination to eliminate unnecessary image data during analysis of the container contents.

Regarding **claim 9**, the Watson et al. and Michelotti et al. combination discloses the elements of claim 8 as described above.

The Watson et al. and Michelotti et al. combination does not explicitly disclose that 15 to 50%, preferably 20 to 25%, of the outer surface of the container is covered.

However, Watson et al. discloses test tubes with labels that cover 20 to 25% of the container (see figures 2, 5 and 8A, numeral 14).

Therefore, as it has already been established that it would have been obvious at the time the invention was made to one of ordinary skill in the art to blank out the labels of the Watson et al. and Michelotti et al. combination, 15 to 50%, preferably 20 to 25%, of the outer surface of the container is covered as a result.

20. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Watson et al. and Schemmel et al (US 6,175,646).

Watson et al. discloses a method characterized in that the image recording device is used to produce an image of the body fluid in a first container (image of figure 1, numeral 14) and an image of a subsequent second container (subsequent tube image) for the purpose of determining the type and size of the second container (determining what tube type and its specimen volume).

Watson et al. does not disclose that both images are produced simultaneously.

Schemmel et al. teaches a method in the same field of endeavor of object inspection, characterized in that multiple images are produced simultaneously ("captures one or more die images simultaneously" at col. 1, line 67) prior to comparison to reference images ("compared to silicon dies images" at col. 2, line 3).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize the simultaneous imaging of Schemmel to produce the container images of Watson et al. to be able to process more units at once (see Schemmel at col. 5, line 67- col. 6, line 7).

21. Claims 12 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Itsuzaki et al.

Regarding **claim 12**, Itsuzaki et al. discloses the elements of claim 11 as described in the 102 rejection above.

Itsuzaki et al. does not disclose that the color image of the body fluid and/or container are/is converted automatically into a gray value image.

However, Itsuzaki et al. does show that the sample analysis can be done using grey-level images in another embodiment ("visual sensor for taking an image of the separated blood 1 and outputting the image as monochromatic image data" at col. 3, line 10; figure 1). Furthermore, it is well-known in the art to convert color images to grey-level images prior to further analysis as a form of image segmentation.

Therefore it would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize a grey-level conversion of the color data of Itsuzaki et

al. to maximize the contrast between the relevant image information and background information.

Regarding **claim 18**, Itsuzaki et al. discloses a method characterized in that in order to identify the separating means and/or the blood clot in a centrifuged sample of body fluid (figure 7, numeral 1), each pixel row of the image is scanned ("projection data row obtained by adding image data in every one of all horizontal lines in the boundary detection region" at col. 3, line 49), and the transition from dark color or brightness values to brighter color or brightness values is detected ("positions of peak differential values may be obtained" at col. 3, line 52, which correspond to image data values with particular intensities; the peak values indicate transition points) and defined as phase boundary between blood clot and a separating means or between the separating means and serum ("detects the upper boundary position 5 of serum components" at col. 3, line 33; "lower boundary position 6 of serum components detected" at col. 3, line 54).

Itsuzaki et al. does not disclose that the image is scanned from bottom to top.

However, at the time of the invention, it would have been obvious to a person of ordinary skill in the art to scan the image from bottom to top as one of ordinary skill in the art would have expected Applicant's invention to perform equally well with either the scan direction of Itsuzaki et al. or the claimed bottom to top scan direction because both scan directions perform the same function of detecting image intensities such that transition points between sample components can be found.

22. Claim 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Watson et al. and Itsuzaki et al.

Regarding **claim 13**, Watson et al. discloses a method characterized in that for the purpose of detecting the type and size of the container, changes in color value and/or brightness value are determined and compared with the data of known containers ("Subtract A1 of current image from A1 of reference using LUT" at page 22, line 18; color changes over the pixels of the sub-images are observed by this difference).

Watson et al. does not disclose that a number of vertical lines are laid in the image of the container.

Itsuzaki et al. teaches a method for analyzing body fluids ("specimen testing method" at col. 1, line 5) characterized in that a number of vertical lines are laid in the image of the container ("position detecting lines 16a to 16n for detecting the concentration change points are provided in the vertical direction" at col. 3, line 38), the color values and/or brightness values of the pixels lying on these lines are detected (the image data is evaluated according to intensities), and changes in color value and/or brightness value are determined ("positions 17a to 17n at peaks of differential values are detected" at col. 3, line 44, which correspond to image data values with particular intensities).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize the detection lines of Itsuzaki et al. to analyse the image data of

Watson et al. as a reliable way to extract vertical transition points such that the image data may be discerned.

Regarding **claim 14**, Watson et al. discloses a method characterized in that a handling apparatus (figure 5, numeral 46) is controlled with the aid of the data determined for the container ("Information concerning the placement of tubes 14, 15 in specific destination racks is also sent to the computerised laboratory information management system" at page 25, line 3).

23. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Watson et al. and Minden (US 6,342,143).

Watson et al. discloses a method characterized in that one or more detail images are produced ("Create sub-images or areas used for liquid level detection" at page 22, line 30).

Watson et al. does not disclose that the detail images are combined by means of the image processing software to form an overall image.

Minden teaches a method in the same field of endeavor of biological sample analysis ("imager is provided for providing images of samples" at col. 2, line 39) characterized in that one or more detail images are produced ("tiled images" at col. 7, line 5) that are combined by means of the image processing software to form an overall image ("computationally assembled to create one complete image" at col. 7, line 10; "CCD camera is connected to computer" at col. 4, line 65).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize the composite image assembly of Minden to combine the sub-images of Watson et al. such that the user can be presented with one image of the relevant image areas rather than viewing them separately.

24. Claims 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Itsuzaki et al. and Watson et al.

Regarding **claim 17**, Itsuzaki et al. discloses the elements of claim 16 as described in the 102 rejection above.

Itsuzaki et al. does not disclose that the background region is removed from the image computationally.

Watson et al. teaches a method for analyzing body fluids ("analyzer is arranged to detect the level of the sample" at page 6, line 23) characterized in that the background region is removed from the image computationally ("Blank out unused areas (cap area, bottom radius) using the physical properties of the tube" at page 23, line 1).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize the image blanking of Watson et al. on the image data of Itsuzaki et al. to eliminate unnecessary image data during analysis of the container contents.

Regarding **claim 19**, Itsuzaki et al. discloses the elements of claim 18 as described in the 103 rejection above.

Itsuzaki et al. does not disclose that the image region determined for the separating means and/or the blood clot is removed from the image computationally.

Watson et al. teaches a method for analyzing body fluids ("analyzer is arranged to detect the level of the sample" at page 6, line 23) characterized in that the background region is removed from the image computationally ("Blank out unused areas (cap area, bottom radius) using the physical properties of the tube" at page 23, line 1).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize the image blanking of Watson et al. on the separating means and blood clot image data of Itsuzaki et al. to eliminate unnecessary image data during analysis of the container contents.

25. Claims 20 and 24/20 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Itsuzaki et al. and Hsu (US 5,640,468).

Regarding **claim 20**, Itsuzaki et al. discloses a method characterized in that in order to identify blood serum/plasma and/or separating means and/or blood clot, regions of pixels with similar color values are determined ("positions of peak differential values may be obtained" at col. 3, line 52, which correspond to image data values with particular intensities; the peak values indicate transition points), and the resulting regions are defined as serum, separating means and/or blood clot ("detects the upper boundary position 5 of serum components" at col. 3, line 33; "lower boundary position 6 of serum components detected" at col. 3, line 54).

Itsuzaki et al. does not disclose a region-grow method.

Hsu teaches a method in the same field of endeavor of object recognition ("object/feature extraction by generating uniform regions" at col. 1, line 7) characterized in that by means of a region-grow method ("region-growing method" at col. 12, line 44), regions of pixels with similar color values are determined ("segmentation yields a segmentation map that corresponds to a visual segmentation of the color map" at col. 12, line 47).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize the region-growing of Hsu to segment the image data of Itsuzaki et al. to "provide a method for segmenting an image with minimal mathematical computation" at col. 3, line 37).

Regarding **claim 24/20**, Itsuzaki et al. discloses a method characterized in that in order to determine the volume of the blood serum, upper and lower limits of the serum region are determined automatically ("detects the upper boundary position 5 of serum components" at col. 3, line 33; "lower boundary position 6 of serum components detected" at col. 3, line 54), and the volume is calculated automatically with the aid of the diameter of the container ("serum component amount N is calculated from the diameter M of a test tube" at col. 4, line 8).

26. Claims 21, 24/21 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Itsuzaki et al. and Hsu as applied to claim 20 above, and further in view of Rowe et al. (US 7,126,682).

Regarding **claim 21**, the Itsuzaki et al. and Hsu combination discloses a method characterized in that it detects solid particles in the serum and/or plasma ("clot components" at col. 3, line 5) using color values ("color digital image data" at col. 4, line 35).

The Itsuzaki et al. and Hsu combination does not disclose that in order to detect solid particles in the serum and/or plasma, the region corresponding to the serum is compared with stored color values of reference samples and classified as "clear" or "not clear".

Rowe et al. teaches a method in the same field of endeavor of biological sample analysis ("perform spectroscopic determinations on biological media" at col. 3, line 58) characterized in that in order to detect solid particles ("quantity of an analyte" at col. 3, line 59) in the sample ("fluids measured either in-vivo or in-vitro derived from humans" at col. 3, line 65), the region corresponding to the sample is compared with stored values of reference samples and classified ("checking for sample quality and consistency with a known class of samples" at col. 3, line 61).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize the sample quality comparison of Rowe et al. in the system of Watson et al. to help ensure that only samples of sufficient quality are processed such that relevant diagnostic information can be obtained.

The Itsuzaki et al., Hsu and Rowe et al. does not explicitly state that the samples are classified as "clear" or "not clear".

However, the method does check for sample quality and clarity is a measure of sample quality.

Therefore, it would have been obvious at the time the invention was made to one of ordinary skill in the art to classify the samples of the Itsuzaki et al., Hsu and Rowe et al. combination based on clarity as another way of quantifying the quality of the sample such that only samples of sufficient quality are processed.

Regarding **claim 24/21**, Itsuzaki et al. discloses a method characterized in that in order to determine the volume of the blood serum, upper and lower limits of the serum region are determined automatically ("detects the upper boundary position 5 of serum components" at col. 3, line 33; "lower boundary position 6 of serum components detected" at col. 3, line 54), and the volume is calculated automatically with the aid of the diameter of the container ("serum component amount N is calculated from the diameter M of a test tube" at col. 4, line 8).

Regarding **claim 27**, the Itsuzaki et al., Hsu and Rowe et al. combination discloses a method characterized in that the serum is classified overall as "good" when the majority of the pixels are classified as "good", and in that the serum is classified overall as "not good" when the majority of the pixels are classified as "not good" (as established, the quality of the sample is checked by comparing the current sample to reference samples. As such, it would only follow that a majority of pixels classified in either category would indicate an overall sample quality).

27. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Itsuzaki et al., Hsu and Rowe et al. as applied to claim 21 above, and further in view of Yamazaki et al. (US 5,880,835).

The Itsuzaki et al., Hsu and Rowe et al. combination discloses the elements of claim 21 as described in the 103 rejection above.

The Itsuzaki et al., Hsu and Rowe et al. combination does not disclose that the particles are classified in terms of shapes or colors.

Yamazaki et al. teaches a method in the same field of endeavor of biological sample analysis ("apparatus for investigating urinary sediments in urine, or blood cells in blood" at col. 1, line 15) characterized in that particles are classified in terms of shapes or colors ("classifies each particle into corresponding shape classes" at col. 19, line 37).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize the shape classification of Yamazaki et al. to classify the image data of the Itsuzaki et al., Hsu and Rowe et al. combination such that "particles can be counted accurately and exact particle concentrations can be obtained" at col. 19, line 53).

28. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Itsuzaki et al. and Hsu as applied to claim 20 above, and further in view of Watson et al.

The Itsuzaki et al. and Hsu combination discloses the elements of claim 20 as described in the 103 rejection above.

The Itsuzaki et al. and Hsu combination does not disclose that the image region determined for the separating means and/or the blood clot is removed from the image computationally.

Watson et al. teaches a method for analyzing body fluids ("analyzer is arranged to detect the level of the sample" at page 6, line 23) characterized in that the background region is removed from the image computationally ("Blank out unused areas (cap area, bottom radius) using the physical properties of the tube" at page 23, line 1).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize the image blanking of Watson et al. on the separating means and blood clot image data of the Itsuzaki et al. and Hsu combination to eliminate unnecessary image data during analysis of the container contents.

29. Claim 25, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Watson et al. and Rowe et al.

Regarding **claim 25**, Watson et al. discloses a method characterized in that a color value is determined for each pixel for the purpose of color analysis of a serum ("Take a picture of full field view with 24 bit RGB colour depth" at page 22, line 7; "detection of the sample level" at page 22, line 28; "volume of plasma or serum" at page

23, line 25), and is compared with stored color values ("Process the current sub-image against all calibrated tubes" at page 22, line 13).

Watson et al. does not disclose that the sample is compared with stored values of classified reference samples, and is classified as "good" or "not good".

Rowe et al. teaches a method in the same field of endeavor of biological sample analysis ("perform spectroscopic determinations on biological media" at col. 3, line 58) characterized in that the sample is compared with stored values of classified reference samples ("consistency with a known class of samples" at col. 3, line 61), and is classified as "good" or "not good" ("sample quality" at col. 3, line 61, which implies a determination of whether the sample is good or not).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize the sample quality comparison of Rowe et al. in the system of Watson et al. to help ensure that only samples of sufficient quality are processed such that relevant diagnostic information can be obtained.

Regarding **claim 29**, Watson et al. discloses a method characterized in that images are produced ("sub-images of areas used for tube identification" at page 21, line 25), classified into classes (every class is a particular tube type with physical characteristics, gel attributes and specimen types) and stored in data file/files in order to produce reference data ("Save sub-images and data to storage media" at page 22, line 1).

Watson et al. does not disclose that the images are known samples.

Rowe et al. teaches a method in the same field of endeavor of biological sample analysis ("perform spectroscopic determinations on biological media" at col. 3, line 58) characterized in that known samples are produced, classified into classes and stored in data file/files in order to produce reference data ("checking for sample quality and consistency with a known class of samples" at col. 3, line 61).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize the sample quality comparison of Rowe et al. in the system of Watson et al. to help ensure that only samples of sufficient quality are processed such that relevant diagnostic information can be obtained.

Regarding **claim 30**, Watson et al. discloses a method characterized in that color features ("Create a look-up table for RGB values using the average values from the black/white colour calibration of the current image and reference images" at page 22, line 15) are extracted at least once for all the images of the individual classes ("Process the current sub-image against all calibrated tubes" at page 22, line 13).

30. Claim 26/24/20 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Itsuzaki et al. and Hsu as applied to claim 24/20 above, and further in view of Bills (US 6,366,319).

The Itsuzaki et al. and Hsu combination discloses a method characterized in that a comparison is undertaken in a color space ("hue information, H, luminance information V, and saturation information, C" Itsuzaki et al. at col. 4, line 40).

The Itsuzaki et al. and Hsucombination does not disclose that the color space is a “CIE lab” space.

However, it is common knowledge in the art to convert from a color space to CIE lab space (“convert the interpolated CYW color planes to CIELAB color space” Bills at col. 14, line 56).

Therefore, it would have been obvious at the time the invention was made to one of ordinary skill in the art to convert the color space of the Itsuzaki et al. and Hsu combination to conduct the comparison as an "advantage to using CIELAB color space is that the color gamut or saturation can be limited to reduce color aliasing or color noise" at col. 15, line 1).

31. Claim 26/24/21 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Itsuzaki et al., Hsu and Rowe et al. as applied to claim 24/21 above, and further in view of common knowledge as evidenced by Bills.

The Itsuzaki et al., Hsu and Rowe et al. combination discloses a method characterized in that a comparison is undertaken in a color space ("hue information, H, luminance information V, and saturation information, C" Itsuzaki et al. at col. 4, line 40).

The Itsuzaki et al, Hsu and Rowe et al. combination does not disclose that the color space is a “CIE lab” space.

However, it is common knowledge in the art to convert from a color space to CIE lab space (“convert the interpolated CYW color planes to CIELAB color space” Bills at col. 14, line 56).

Therefore, it would have been obvious at the time the invention was made to one of ordinary skill in the art to convert the color space of the Itsuzaki et al., Hsu and Rowe et al. combination to conduct the comparison as an "advantage to using CIELAB color space is that the color gamut or saturation can be limited to reduce color aliasing or color noise" at col. 15, line 1).

32. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Watson et al.

Watson et al. discloses the elements of claims 37-39 as described in the 102 rejections above.

Watson et al. does not explicitly disclose that the computer program product is stored on a hard disk, a floppy disk, a CD ROM or a storage tape.

However, due to the fact that the Watson et al. reference utilizes a computer, it is well known in the art that computers make use of hard disks, floppy disks, CD ROMs or storage tapes to realize the functions of the programs they contain.

Conclusion

33. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,985,215 is pertinent as disclosing a biological sample analysis apparatus and method.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATRINA FUJITA whose telephone number is (571)270-1574. The examiner can normally be reached on M-Th 8-5:30pm, F 8-4:30pm.

34. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vikkram Bali can be reached on (571) 272-7415. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Katrina Fujita/
Examiner, Art Unit 2624

/Vikkram Bali/
Supervisory Patent Examiner, Art Unit 2624